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IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF VIRGINIA ROANOKE DIVISION

CHESTER T. KALINOSKI	
Plaintiff,	
v.)	Civil Action No.:
NEW ENGLAND COMPOUNDING	
PHARMACY, INC. D/B/A NEW ENGLAND)	
COMPOUNDING CENTER	
Serve: Gregory Conigliaro, Its Registered Agent)	
697 Waverly Street	
Framingham, MA 01701,	
)	
)	
MEDICAL SALES MANAGEMENT, INC.	
Serve: Secretary of the Commonwealth of)	
Virginia, Janet Vestal Kelly	
Service of Process Department)	
P.O. Box 2452	
Richmond, VA 23218-2452	
and)	
)	
BARRY J. CADDEN,	
Serve at: 13 Manchester Drive	
Wrentham, MA 02093	
)	
Defendants.	

COMPLAINT

Chester T. Kalinoski ("Kalinoski" or "Plaintiff"), by counsel, states this Complaint against New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), Medical Sales Management, Inc. ("MSM"), and Barry J. Cadden ("Cadden") (hereinafter collectively referred to as the "defendants"):

Preliminary Statement

1. This lawsuit arises from the unnecessary fungal meningitis infection and subsequent

hospitalization of Chester Kalinoski. In 2012, Kalinoski had been experiencing significant lower back pain associated with degenerative disease and narrowing of the spine. Kalinoski's doctors recommended extensive back surgery in order to address the problem, and before that surgery they referred him for an epidural steroid injection as a preliminary measure. Instead of easing his pain, the injection nearly killed him.

Kalinoski became gravely ill and was hospitalized for a period of nearly three weeks because the steroid shot, manufactured, advertised and distributed by the defendants, was adulterated and contaminated with fungus or mold bearing pathogens that were injected into his central nervous system along with the immune system suppressing steroid. As the fungus grew inside Kalinoski's spinal fluid, he developed fungal meningitis, severely inflaming the tissues lining his brain and spinal cord. This lawsuit seeks compensation from the defendants for Kalinoski's unnecessary infection and personal injury.

Parties

- 2. Kalinoski is a citizen of the Commonwealth of Virginia.
- 3. NECC is a Massachusetts corporation that maintains its principal place of operations at 697 Waverly Street, in Framingham, Massachusetts.
- 4. MSM is a Massachusetts corporation that maintains its principal place of operations at 701 Waverly Street, Framingham, Massachusetts.
- 5. Cadden, who was at all relevant times the responsible pharmacist for NECC, is a Massachusetts resident.

Jurisdiction and Venue

6. This matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

- 7. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a).
- 8. A substantial part of the events or omissions giving rise to this claim occurred in this judicial district.
 - 9. Venue is proper in this Court pursuant to at least 28 U.S.C. § 1391(b)(2).

Factual Background

The Defendants' Operations

- 10. NECC is jointly owned by Cadden, his wife, Lisa Cadden and her brother, Gregory Conigliaro.
 - 11. The defendants operated a compounding pharmacy in Framingham, Massachusetts.
- 12. Compounding pharmacies engage in mixing (or "compounding") drug products for specific patients, pursuant to a valid prescription.
- 13. Because they typically compound drug products in forms that are not commercially available, compounding pharmacies are not regulated by the FDA.
- 14. Rather, compounding pharmacies are generally regulated under state law applicable to pharmacies and pharmacists. Although it operates in Massachusetts, NECC must also comply with Virginia law in order to fill prescriptions in Virginia. It must be licensed and registered with the Virginia Board of Pharmacy.
- 15. MSM is a separate corporate entity from NECC. Upon information and belief, at all relevant times, MSM served as the marketing arm for New England Compounding, providing marketing and advertising services, promoting the compounding business at medical trade shows nationwide, "cold-calling" potential customers, calling existing customers, and managing NECC's online operations.

- 16. Cadden is the pharmacist in charge of NECC's operations, and was listed as such in NECC's registration as a nonresident pharmacy in Virginia.
- 17. As pharmacist in charge, Cadden was at all relevant times personally responsible to ensure that NECC's operations complied with Virginia laws. Va. Code § 54.1-3434.1 (any non-resident pharmacy "shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter . . ." (emphasis added).
- 18. Furthermore, as pharmacist in charge of NECC, Cadden was at all times personally responsible to supervise NECC's operations at its facility in Framingham, Massachusetts. Va. Code § 54.1-3432 ("Every pharmacy shall be under the *personal supervision* of a pharmacist on the premises of the pharmacy.") (emphasis added).
- 19. The defendants are in the business of compounding and manufacturing medications and drugs, including methylprednisolone acetate. The brand name of this drug, Depo-Medrol, is produced by the FDA-regulated company, Pharmacia & Upjohn Company, a Division of Pfizer, Inc. Other FDA-regulated drug manufacturers produce generic versions of this drug.
- 20. Rather than producing small quantities of this knock-off Depo-Medrol, NECC produced vast batches of this drug, thousands at a time. It then acted as a wholesale distributor.
- 21. The defendants compounded and manufactured medications, including methylprednisolone acetate, that were contaminated with fungus, mold and other contaminants.
- 22. Under Virginia Code §54.1-3435.01(A), non-resident pharmacies that engage in wholesale distribution of prescription drugs into the Commonwealth of Virginia must register with the Virginia Board of Pharmacy, in addition to registering as a non-resident pharmacy.

- 23. NECC is and was registered in the Commonwealth of Virginia as a non-resident pharmacy, but is not and was not registered as a wholesale distributor of prescription drugs as required by Virginia Code §54.1-3435.01(A).
- 24. Under Virginia law, the compounding pharmacist must ensure compliance with USP-NF standards (United States Pharmacopeial National Formulary). Virginia Code § 54.1-3410.2(E).
- 25. Pharmacists and pharmacies may not engage in "the regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products." Virginia Code § 54.1-3410.2(H)(2).
- 26. As well as other drugs, the defendants produced methylprednisolone acetate without preservative, which they then sold to clinics, hospitals and other healthcare providers in bulk, packaging the drug in single dosage vials.
- 27. Such large-scale production of a commercially available drug is illegal under Virginia Code § 54.1-3410.2(H)(2).
- 28. NECC is not accredited by the Pharmacy Compounding Accreditation Board ("PCAB") or any other similar organization, such as The Joint Commission, that offers independent assurance as to the quality and competence of compounding pharmacies that meet certain requirements.
- 29. The drug at issue was to be used in epidural steroid injections allowing direct contact with the central nervous system. It was produced from non-sterile ingredients which then had to be rendered sterile as a finished product, thus making the methylprednisolone acetate a high-risk compound. It was also produced without preservatives. Thus, although all drugs should be

produced in a highly sterile environment, these drugs in particular must be. Additionally, sterilization techniques and sterility testing are crucial to properly producing such drugs.

- 30. However, the defendants purposefully maintained the supposedly sterile NECC pharmacy in an aged building that is surrounded by a waste recycling center owned by one of the co-owners of NECC, Gregory Conigliaro. This facility, called Conigliaro Enterprises, receives many varieties of garbage and waste which are sorted, stored, and manipulated just outside the back door of the NECC facility. A photograph showing the rear wall and backyard of the "pharmacy" is attached as **Exhibit A**.
- 31. It is difficult to distinguish where NECC ends and the waste recycling center begins, if there is such a distinction in fact; but, the waste facility lists its address as 701 Waverly Street, Framingham, Massachusetts, and operates under the name "Conigliaro Industries." NECC lists its address as 697 Waverly Street. MSM lists its address as 701 Waverly Street, the same as Conigliaro Industries.
- 32. The conditions in which the defendants produced their products were unsanitary and unsterile. NECC failed to meet basic quality and sterility standards; and it failed to properly test the drugs at issue for sterility prior to releasing them. As a result, thousands of adulterated products manufactured by NECC were then released into the stream of commerce throughout the United States of America, including at least two clinics in the Commonwealth of Virginia.
- 33. The drug at issue in this case is a steroid which the defendants knew would be injected into patients so as to enter or potentially enter the central nervous system. The defendants also knew that such steroids act as immune-suppressing agents, thus weakening the patient's natural ability fight off pathogens that could possibly be included in the injection. The defendants also knew that the central nervous system is a relatively closed system, making treatment options more

difficult in the event of an adulterated invasion. Notwithstanding this knowledge, the defendants chose to operate NECC's facility in the same complex as the waste facility, chose to produce such drugs in bulk batches (making mistakes more likely), chose not to properly sterilize the drugs, and chose not to have the drugs sufficiently tested by an FDA-approved testing facility before release for sale.

Kalinoski's Medical Timeline

- 34. In mid-May of 2012, Kalinoski injured his back while clearing lumber from his property in Floyd County, Virginia.
- 35. The back pain grew steadily worse, and eventually Kalinoski sought the advice of his general practitioner, Dr. Donald Smith.
- 36. Dr. Smith diagnosed him with a bulging disk in his lower back, and Kalinoski underwent three weeks of physical therapy in July of 2012.
- 37. After the three weeks had produced little to no progression in his symptoms, Kalinoski was scheduled for a Magnetic Resonance Imaging (MRI) scan at the Carilion Spine Center in Roanoke, Virginia.
- 38. The MRI, taken on August 21, indicated spinal stenosis (narrowing of the spine) and degenerative disease in his lumbar discs at L4-L5.
- 39. The neurosurgeon who reviewed the MRI scans, Dr. Gary R. Simonds, recommended that Kalinoski receive an epidural steroid injection as a stop-gap measure before undergoing more intensive treatment.
- 40. Dr. Simonds referred him to Insight Imaging Roanoke, an image-guided pain management practice, for the epidural steroid injection. The typical method for receiving such an injection requires radiological facilities that allow the proper placement of the shot in exactly the

right place with the assistance of equipment such as a fluoroscope. An anesthesiologist or an interventional radiologist usually performs such a procedure.

- 41. Kalinoski received the injection at the clinic on or about August 29, 2012.
- 42. Almost immediately after the injection, Kalinoski began experiencing considerable pain in his back. He had driven to the clinic himself, and was undergoing such pain that he realized he was unable to drive home. He called his primary care doctor, who recommended that Kalinoski be taken by ambulance to the emergency room. An ambulance was called, and he was taken directly to the emergency room at Roanoke Memorial Hospital.
- 43. After eight hours on a gurney in the emergency room, his pain had subsided and he was able to go home. Over the next few weeks, his back pain never truly subsided, and he experienced back spasms.
- 44. In fact, the back spasms extended from his quadriceps to his hamstrings, and by early September he was experiencing severe headaches, fever, nausea and vomiting.
 - 45. From September 6 to September 8, 2012, he was essentially bedridden at home.
- 46. Kalinoski's surgeon advised him to undergo spinal laminectomy, an extensive surgery that involves cutting out bone growths and spurs that press against the spinal nerves. The surgery was scheduled for October 12, 2012.
- 47. However, Kalinoski's symptoms of severe headaches, fever, nausea and vomiting were still present in early October, when NECC issued a recall of its products (including the type of medication that was injected into Kalinoski).
- 48. On Monday, October 8, 2012, Kalinoski received a phone call from Dr. Smith, who told him that he should be evaluated for fungal meningitis.

- 49. Kalinoski went to Roanoke Memorial Hospital, where the medical performed a spinal tap and diagnosed him as suffering from fungal meningitis.
- 50. Kalinoski was hospitalized in serious condition from October 8 to October 26, 2012—a period of almost three weeks.
- 51. Kalinoski's life has been profoundly impacted by the meningitis. Treatment for his ongoing back pain has been indefinitely delayed because of the infection. He continues to suffer significant back pain, in addition to the primary problems caused by the infection itself.
- 52. Kalinoski's fungal meningitis was a direct and proximate result of having methylprednisolone acetate made by the defendants and contaminated with fungus, mold and other contaminants injected into his spinal cavity.
- 53. As a proximate result of the defendants' actions, Kalinoski has suffered and continues to suffer serious bodily harm, mental anguish, economic loss (including but not limited to medical expenses) and other damages.

COUNT I: NEGLIGENCE PER SE

- 54. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.
- 55. Virginia Code Section 8.01-221 establishes that a person who is harmed by violation of a statute may recover for such harm.
 - 56. Virginia law also establishes that:

. . . the violation of a statute or municipal ordinance adopted for public safety constitutes negligence because the violation is the failure to abide by a particular standard of care prescribed by a legislative body. A party relying on negligence per se does not need to establish common law negligence provided the proponent of the doctrine produces evidence supporting a determination that the opposing party violated a statute enacted for public safety, that the proponent belongs to the class of persons for whose benefit the statute was enacted and the harm suffered was of the type against which the statute was designed to protect, and that the statutory violation was a proximate cause of the injury. Halterman v.

Radisson Hotel Corp., 259 Va. 171, 176-77, 523 S.E. 2d 823, 825 (2000); Virginia Elec. & Power Co. v. Savoy Constr. Co., 224 Va. 36, 45, 294 S.E. 2d 811, 817 (1982)

Schlimmer v. Poverty Hunt Club, 268 Va. 74, 78-79, 597 S.E.2d 43, 46 (2004) (quotations omitted).

- 57. Virginia Code Sections 54.1-3400 *et seq.* (collectively known as "The Drug Control Act") are statutes enacted for public safety, in that they protect the public from the release of substandard and otherwise unreasonably dangerous pharmaceutical drugs and medications into the stream of Virginia commerce.
- 58. As a Virginia resident and consumer of a drug regulated by the Virginia Drug Control Act, Kalinoski belongs to the class of persons for whose benefit those statutes were enacted.
- 59. A drug is deemed adulterated under Virginia law if it has been produced, prepared, packed, or held under insanitary conditions whereby it has been rendered injurious to health. Va. Code §54.1-3461(A)(2).
- 60. Additionally, a drug is considered adulterated if it purports to be a drug recognized in an official compendium, but fails to meet the quality or purity standards set forth in the compendium or the federal act. Va. Code §54.1-3461(B).
- 61. By manufacturing and selling an adulterated drug into the stream of Virginia commerce, the defendants violated Virginia Code §§ 54.1-3457(1), which is part of the Virginia Drug Control Act.
- 62. By negligently adulterating a drug, the defendants violated Virginia Code §§ 54.1-3457(2), which is part of the Virginia Drug Control Act.
- 63. By failing to adhere to proper quality control standards in producing the drug given to Kalinoski, the defendants failed to comply with USP-NF standards in violation of Virginia Code § 54.1-3410.2(E).

- 64. By engaging in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license to do so issued by the Virginia Board of Pharmacy, the defendants violated Virginia Code § 54.1-3435, which is part of the Virginia Drug Control Act.
- 65. As pharmacist in charge, defendant Cadden was personally responsible for ensuring that NECC did not violate the provisions of the Virginia Drug Control Act. (Va. Code § 54.1-3432).
- 66. The defendants' actions violating Va. Code §§ 54.1-3457(1) and (2), 54.1-3410.2(E), and 54.1-3435 proximately caused Kalinoski's fungal meningitis. His illness occurred as a direct and proximate result of having the defendants' adulterated drug containing a fungal pathogen injected directly into his central nervous system.
- 67. Death or injury of a patient resulting from consumption of or contact with adulterated drugs belongs to the category of harms against which the Virginia Drug Control Act was designed to protect.
- 68. Death or injury of a patient resulting from consumption of or contact with adulterated drugs distributed wholesale by an entity engaging in the wholesale distribution of prescription drugs in this Commonwealth without registration belongs to the category of harms against which Virginia Drug Control Act was designed to protect
- 69. United States Code §§ 21 U.S.C. 301 *et seq*. (collectively known as "The Federal Food, Drug and Cosmetic Act" or "FDCA") are statutes enacted for public safety, in that they protect the public from the release of adulterated, substandard and otherwise unreasonably dangerous pharmaceutical drugs and medications into the stream of U.S. Commerce.

70. Therefore, because the defendants' actions violating each of the above statutes (Virginia Code § 54.1-3457(1), Virginia Code § 54.1-3457(2) and Virginia Code § 54.1-3435)) caused his fungal meningitis and constitute negligence *per se*, Kalinoski is entitled to recovery of damages for the serious bodily harm, mental anguish and economic loss (including but not limited to medical and other expenses) and other damages he suffered as a result of those actions.

COUNT II: NEGLIGENT MANUFACTURE

- 71. Plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.
- 72. The defendants owed a duty to Kalinoski, all other foreseeable users of their products, and the public in general to timely and properly:
 - a. operate in a clean and sterile environment with properly functioning equipment;
 - b. establish quality control measures;
 - c. implement quality control measures;
 - d. manufacture uncontaminated products;
 - e. obtain representative sterility testing for their products for contamination prior to releasing the products into the stream of commerce;
 - f. refrain from releasing contaminated products into the stream of commerce;
 - g. refrain from operating their facility in immediate proximity to a waste recycling center owned and operated by one of NECC's co-owners, and thus causing an inordinately high possibility that their drugs would become contaminated by contact with spores or other contaminants contained in the waste recycling center;
 - h. refrain from producing such a high quantity of drugs that implementing proper quality control measures became difficult or impossible; and
 - i. refrain from engaging in any other act or omission determined during the course of discovery.

- 73. The defendants breached the above duties and acted negligently, in at least the following ways, by failing to timely and properly:
 - j. operate in a clean and sterile environment with properly functioning equipment;
 - k. establish quality control measures;
 - I. implement quality control measures;
 - m. manufacture uncontaminated products;
 - n. quality test their products for contamination prior to releasing the products into the stream of commerce;
 - o. refrain from releasing contaminated products into the stream of commerce;
 - p. refrain from operating their facility in immediate proximity to a waste recycling center owned and operated by one of NECC's co-owners, and thus causing an inordinately high possibility that their drugs would become contaminated by contact with spores or other contaminants contained in the waste recycling center;
 - q. refrain from producing such a high quantity of drugs that implementing proper quality control measures became difficult or impossible; and
 - r. refrain from engaging in any other act or omission determined during the course of discovery.
- 74. The product methylprednisolone acetate administered to Kalinoski was not reasonably safe at the time it left the defendants' control.
- 75. At the time the product left the control of the defendants, a feasible and reasonably implementable alternative production practice was available that would have prevented the harm caused to Kalinoski without significantly impairing the usefulness or desirability of the product and without creating equal or greater risk of harm to others.
- 76. Kalinoski's infection and hospitalization occurred as a direct and proximate result of the defendants' breaches of their duties to him listed above.

COUNT III: STRICT LIABILITY

- 77. The plaintiff hereby incorporates each of the preceding paragraphs as if set out fully herein.
- 78. The defendants manufactured and sold a product that was inherently dangerous for any human use, particularly those involving introduction of the tainted drug into the central nervous system.
- 79. The inherently dangerous nature of the product was present at the time the product left the defendants' control.
- 80. Kalinoski's infection and hospitalization were directly and proximately caused by the introduction of the defendants' inherently dangerous product into his body.

COUNT IV: NEGLIGENT FAILURE TO WARN

- 81. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.
- 82. The defendants were aware that NECC's production quantities exceeded amounts in which they could properly implement necessary quality controls.
- 83. The defendants knew or had reason to know that the drug given to Kalinoski was not produced under conditions that could reasonably ensure quality and sterility.
- 84. On information and belief, the defendants chose not to obtain independent sterility test results from a representative sampling of the applicable batch of this drug from a third party sterility testing facility as other compounding pharmacies do before releasing such drugs. The size of the batches at issue made any such sampling (if done) representative of the thousands of dosages created.

- 85. The defendants knew or had reason to know that compounding medications surrounded by the owner's garbage recycling center would result in increased chances of contaminating such drugs before and during the manufacturing process. These circumstances, while unreasonable and unbelievable under any scenario, further heightened the need to adhere to strict safety, quality, sterility and testing protocols. But, none of this was done. As a result, it was not a matter of "if" adulterated drugs would be produced and sold by NECC, but instead, a matter of when such would occur or when it would occur to such an extent that illness or death resulted. NECC was engaged in what amounted to "Russian-Roulette" with its practices.
- 86. Because of their knowledge of those issues, as well as other things, the defendants knew or had reason to know that their product, the methylprednisolone acetate, was dangerous for its intended uses.
- 87. The defendants had no reason to believe that Kalinoski would realize the dangerous condition of the methylprednisolone acetate.
- 88. Kalinoski could not possibly have contemplated or anticipated the dangerousness of the defendants' product, as it was contained in a single, unremarkable dosage vial.
- 89. By engaging in the acts and omissions described above, and by failing to inform the buyers and foreseeable users of the contamination of the methylprednisolone acetate, the defendants failed to exercise reasonable care to inform users of the dangers associated with the product's use.
- 90. Kalinoski's infection and hospitalization occurred as a direct and proximate result of the defendants' failure to warn.

COUNT V: GROSS NEGLIGENCE

91. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

- 92. Each of the foregoing acts and omissions by the defendants went beyond mere thoughtlessness, inadvertence or error of judgment.
- 93. Such acts and omissions constituted such an utter disregard for the rights of others, and such an utter disregard for prudence, that they amount to complete neglect of the safety of others, including Kalinoski. The defendants' acts and omissions were a heedless and palpable violation of their legal duties respecting Kalinoski's rights. <u>Frazier v. City of Norfolk</u>, 234 Va. 388, 393, 362 S.E.2d 688, 691 (1987).
- 94. Kalinoski's infection and hospitalization occurred as a direct and proximate result of the defendants' grossly negligent acts and omissions.

COUNT VI: BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

- 95. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.
- 96. The defendants had a duty to buyers and foreseeable users such as Kalinoski to provide a product that was not unreasonably dangerous for the use for which it was intended, and was not unreasonably dangerous for other foreseeable uses.
- 97. Despite that duty, the methylprednisolone acetate was unreasonably dangerous for the use for which it was intended—epidural injection into the bodies of patients, including Kalinoski—as well as other reasonably foreseeable uses.
- 98. The methylprednisolone acetate was unreasonably dangerous for the above-stated uses at the time the product left the defendants' hands.
- 99. The unreasonably dangerous condition of the methylprednisolone acetate directly and proximately caused Kalinoski's fungal meningitis.

COUNT VII: BREACH OF IMPLIED WARRANTY OF USE FOR A PARTICULAR PURPOSE

- 100. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.
- 101. The defendants have heavily marketed both NECC itself and the product methylprednisolone acetate at medical trade shows and the like for use in the pain management setting, including but not limited to inclusion in epidural injections for back pain relief.
- 102. The defendants knew or had reason to know that the intermediate buyer, Insight Imaging, planned to use the methylprednisolone acetate in administering epidural injections to patients.
- 103. As such, the defendants knew or had reason to know the particular purpose for which the methylprednisolone acetate was purchased.
- 104. The defendants had reason to know that their skill or judgment was being relied upon to provide appropriate and reasonably safe goods.
- 105. At the time of the sale, the methylprednisolone acetate failed to satisfy the purpose contemplated at the time of sale—to be injected into the central nervous systems of patients such as Kalinoski without causing those patients to suffer unanticipated and unreasonably unsafe side-effects, e.g., fungal meningitis.
- 106. The failure of the product to satisfy the purpose contemplated at the time of sale proximately caused Kalinoski's fungal meningitis.

COUNT VIII: MEDICAL NEGLIGENCE

(defendant Cadden)

107. Plaintiff repeats and re-alleges all allegations contained in the preceding paragraphs as if they were fully set forth herein.

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108. As director of pharmacy and licensed pharmacist in charge of NECC's operations,

Cadden was at all relevant times acting as NECC's agent and / or principal.

109. Cadden had a duty to Kalinoski and other patients receiving these injections to

utilize basic safety and cleanliness standards in the drug manufacturing processes.

110. Cadden had a duty to Kalinoski and other patients receiving these injections to

exercise reasonable care to ensure that the drugs NECC manufactured were sterile and were not

adulterated.

111. Cadden breached his duties to Kalinoski. He failed to utilize basic safety and

cleanliness standards in the drug manufacturing processes, and he failed to exercise reasonable care

to ensure that the drugs he and NECC manufactured were sterile and not adulterated.

112. Cadden's breaches of duty to Kalinoski proximately caused Kalinoski's fungal

meningitis.

113. The plaintiff has suffered extreme mental anguish, serious bodily harm, and has

incurred and will continue to incur significant expenses, including but not limited to medical

expenses.

WHEREFORE, Chester T. Kalinoski, by counsel, moves this Court for judgment against the

defendants, jointly and severally, in the amount of \$5,000,000 plus taxable costs with pre- and post-

verdict interest on all of these amounts, as well as \$350,000 in punitive damages.

PLAINTIFF REQUESTS A TRIAL BY JURY ON ALL ISSUES.

CHESTER T. KALINOSKI,

/s/ J. Scott Sexton

By Counsel

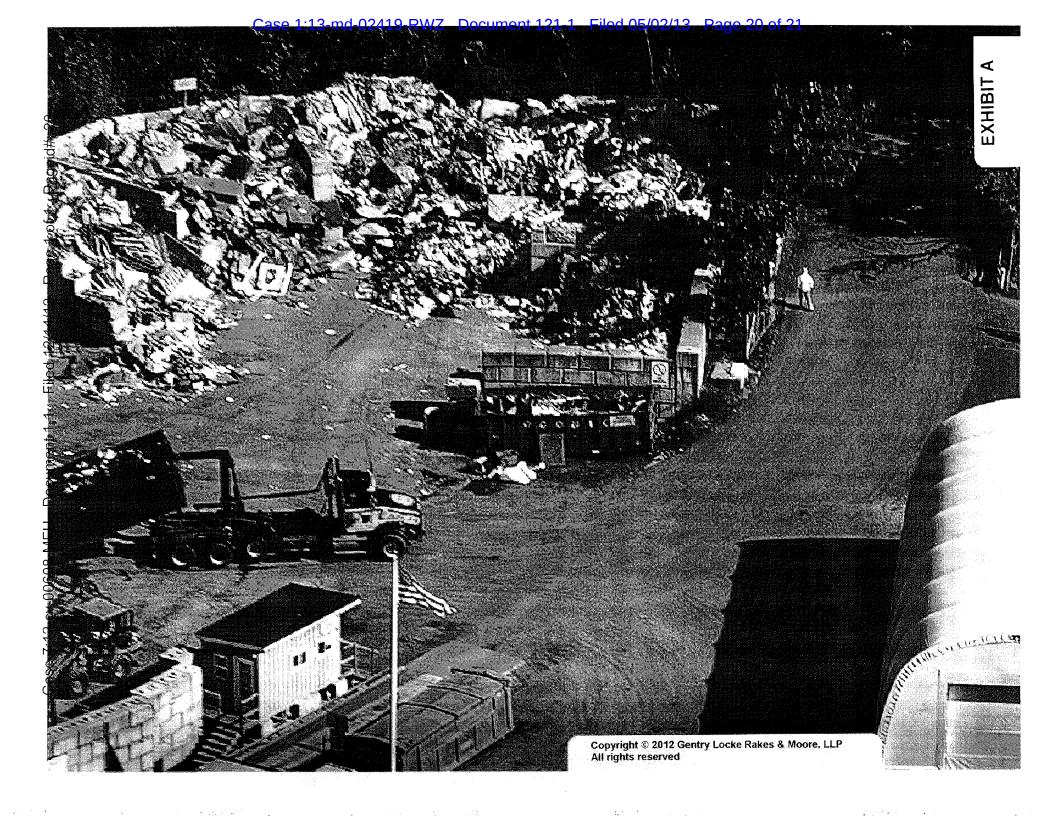
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J. Scott Sexton, Esq. (VSB No. 29284) Anthony M. Russell (VSB No. 44505) Charles H. Smith, III (VSB No. 32891) Benjamin D. Byrd (VSB No. 76560) Daniel R. Sullivan, Esq. (VSB No. 81550) GENTRY LOCKE RAKES & MOORE, LLP 10 Franklin Road, S.E., Suite 800 P. O. Box 40013 Roanoke, Virginia 24022-0013 (540) 983-9300 FAX (540) 983-9400 sexton@gentrylocke.com russell@gentrylocke.com smith@gentrylocke.com byrd@gentrylocke.com sullivan@gentrylocke.com

Counsel for Chester T. Kalinoski



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%±JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS			DEFENDANTS		* *** · · · · · · · · · · · · · · · · ·
Chester T. Kalind	oski				
(b) County of Residence of First Listed Plaintiff Roanoke City (EXCEPT IN U.S. PLAINTIFF CASES)		County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.			
(c) Attorney's (Firm Name	e, Address, and Telephone Number) 540-983-93	300	Attorneys (If Known)		
J. Scott Sexton, Es	q. / Gentry Locke Rakes & Mod	ore, LL	P		
	E, Suite 800, Roanoke, VA 24				
	DICTION (Place an "X" in One Box Only)	III. C	TIZENSHIP OF P (For Diversity Cases Only)	RINCIPAL PARTIES	(Place an "X" in One Box for Plaintiff and One Box for Defendant)
☐ 1 U.S. Government Plaintiff	 3 Federal Question (U.S. Government Not a Party) 	Citiz		TF DEF (I D I Incorporated or Pr of Business In Thi	
2 U.S. Government Defendant	∑ 4 Diversity	Citiz	en of Another State	2 Incorporated and 1	
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IV. NATURE OF SUI	IT (Place an "X" in One Box Only)	l Fo	reign Country		
CONTRACT	TORTS		DRFEITURE/PENALITY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance ☐ 120 Marine	PERSONAL INJURY PERSONAL INJURY 310 Airplane 362 Personal Injury		0 Agriculture 0 Other Food & Drug	☐ 422 Appeal 28 USC 158 ☐ 423 Withdrawal	☐ 400 State Reapportionment ☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Med. Malpracti	ice 🔯 62	25 Drug Related Seizure	28 USC 157	 430 Banks and Banking
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& Enforcement of Judgment 151 Medicare Act	t Slander ☐ 368 Asbestos Persoi ☐ 330 Federal Employers' Injury Product		10 R.R. & Truck 50 Airline Regs.	☐ 820 Copyrights ☐ 830 Patent	☐ 470 Racketeer Influenced and
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3 153 Recovery of Overpayment	Liability 371 Truth in Lendin	g 🗀	LABOR	SOCIAL SECURITY	☐ 850 Securities/Commodities/
of Veteran's Benefits 160 Stockholders' Suits	☐ 350 Motor Vehicle ☐ 380 Other Personal ☐ 355 Motor Vehicle Property Damag		Fair Labor Standards Act	☐ 861 HIA (1395ff) ☐ 862 Black Lung (923)	Exchange 875 Customer Challenge
☐ 190 Other Contract	Product Liability 385 Property Damas	ge 🕡 72	0 Labor/Mgmt. Relations	3 863 DIWC/DIWW (405(g))	12 USC 3410
☐ 195 Contract Product Liability ☐ 196 Franchise	360 Other Personal Product Liabilit Injury	y 13 /3	0 Labor/Mgmt.Reporting & Disclosure Act	☐ 864 SSID Title XVI ☐ 865 RSI (405(g))	☐ 890 Other Statutory Actions ☐ 891 Agricultural Acts
REAL PROPERTY 210 Land Condemnation	CIVIL RIGHTS PRISONER PETITION 3441 Voting 510 Motions to Vac		0 Railway Labor Act 0 Other Labor Litigation	FEDERAL TAX SUITS 3 870 Taxes (U.S. Plaintiff	3 892 Economic Stabilization Act
220 Foreclosure	☐ 442 Employment Sentence		I Empl. Ret. Inc.	or Defendant)	☐ 893 Environmental Matters ☐ 894 Energy Allocation Act
☐ 230 Rent Lease & Ejectment☐ 240 Torts to Land	☐ 443 Housing/ Habeas Corpus: Accommodations ☐ 530 General	İ	Security Act	☐ 871 lRS—Third Party 26 USC 7609	895 Freedom of Information Act
 245 Tort Product Liability 	☐ 444 Welfare ☐ 535 Death Penalty	128 p.	IMMIGRATION		☐ 900Appeal of Fee Determination
290 All Other Real Property	U 445 Amer. w/Disabilities - U 540 Mandanus & O Employment U 550 Civil Rights		52 Naturalization Application 53 Habeas Corpus -		Under Equal Access to Justice
	☐ 446 Amer. w/Disabilities - ☐ 555 Prison Conditio	n	Alien Detainee		 950 Constitutionality of
	Other 440 Other Civil Rights	10 40	55 Other Immigration Actions		State Statutes
Ø 1 Original ☐ 2 R	an "X" in One Box Only) temoved from			ferred from	
And the second s	Cite the U.S. Civil Statute under which you				Judgmont
VI. CAUSE OF ACTI	ION 29 U.S.C. 1332(a) - Divers				
VII. REQUESTED IN COMPLAINT:	N CHECK IF THIS IS A CLASS ACTIO UNDER F.R.C.P. 23		EMAND \$ 5,000,000.00	CHECK YES only JURY DEMAND:	if demanded in complaint:
VIII. RELATED CAS IF ANY	SE(S) (See instructions): JUDGE			DOCKET NUMBER	
DATE	SIGNATURE OF A	TTORNEY	OF RECORD/		
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